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PATENT DOCKET 206,588

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**APPLICANT: LEONE ET AL.**

**EXAMINER:**

**SERIAL NO.: 10/500,665**

**ART UNIT: 1615**

**FILED: June 28, 2004**

**FOR: BAG3 NUCLEOTIDE AND  
PROTEIN SEQUENCES TO BE  
USED IN THE RESEARCH  
DIAGNOSTICS AND THERAPY  
FOR CELL DEATH INVOLVING  
DISEASES**

**August 25, 2005**

**STATEMENT OF FILING BY EXPRESS MAIL 37 C.F.R. § 1.10**

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**INFORMATION DISCLOSURE STATEMENT**

**Honorable Commissioner of Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450**

**Sir:**

This Information Disclosure Statement (hereinafter sometimes referred to as "IDS") is submitted in accordance with 37 C.F.R. §§1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the

above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. §1.97, as it is filed:

(Check one of the boxes opposite A-D)

☐ A. within three months of the filing date of the above-identified national application or within three months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in the above-identified international application.

☒ B. before the mailing date of a first office action on the merits.

☐ C. after the times set forth in (A) and (B) above, but before the mailing date of either a final action under 37 C.F.R. §1.113 or a notice of allowance under 37 C.F.R. §1.311, and the necessary statement pursuant to 37 C.F.R. §1.97(e) appears below (see box "i") or the necessary fee is enclosed (see box "ii" below).

(check one of the boxes opposite "i" or "ii" below)

☐ i. (check the applicable statement)

☐ I, the undersigned, hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

☐ I, the undersigned, hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

☐ ii. A check for the fee set forth in 37 C.F.R. §1.17(p), presently believed to be \$ 240.00, is enclosed.

☐ D. after the times set forth in (A), (B), and (C) above, but before payment of the issue fee, since Applicant petitions for the consideration of this Information Disclosure Statement by a petition enclosed herewith pursuant to 37 C.F.R. §1.97(d)(2), a check for the petition fee set forth in 37 C.F.R. §1.17(i), presently believed to be \$ 130.00, is enclosed, and the necessary statement pursuant to 37 C.F.R. §1.97(e) appears below:

(check the applicable statement)

☐ I, the undersigned, hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

☐ I, the undersigned, hereby state that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

2. In accordance with 37 C.F.R. §1.98(a)(1), this IDS includes a list on form PTO-1449 of all patents, publications, or other information submitted for consideration by the Office, incorporated into this IDS as an attachment hereto. Pursuant to 37 C.F.R. §1.98(b): (i) each U.S. patent listed is identified by patentee, patent number, and issue date; (ii) each foreign patent or published foreign patent application is identified by the country or patent office which issued the patent or published the application, an appropriate document number, and the publication date indicated on the patent or published application; and (iii) each publication is identified by author (if any), title, relevant pages of the publication, date, and place of publication. A legible copy of each document listed is attached and incorporated into this IDS, except that no copy of any U.S. patent application is included pursuant to 37 C.F.R. §1.98(a)(2)(iii) and except as explained below.

(check the boxes opposite A and/or B and fill in blanks, if appropriate)

☐ A. Document(s) \_\_\_\_\_ is (are) substantively cumulative to document(s) \_\_\_\_\_, and, in accordance with 37 C.F.R. §1.98(c), only a copy of each of the latter document(s) is (are) attached.

☐ B. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon for an earlier filing date under 35 U.S.C. §120:

[insert serial numbers and filing dates of prior applications]

These documents are identified by attaching hereto copies of the forms PTO-892 and/or PTO-1449 from the files of the prior application(s) and Applicant requests that they be considered and made of record in this application in accordance with 37 C.F.R. §1.98(d). Pursuant to 37 C.F.R. §1.98(d), copies of these documents need not be provided with this IDS.

(check paragraphs 3 and/or 4, if applicable)

☐ 3. Document(s) \_\_\_\_\_ is (are) not in the English language. In accordance with 37 C.F.R. §§1.98(a)(3), 1.98(c), it is stated that:

(check the applicable statement(s))

☐ English translation(s) of the document(s) \_\_\_\_\_ (or of the pertinent portions thereof) is (are) enclosed and, thus no concise explanation of their relevance is required, (see M.P.E.P., §609, p. 600-92).

☐ English-language equivalent(s) of the document(s) \_\_\_\_\_ (or of the pertinent portions thereof) which is (are) in fact translation(s) of the document(s) is (are) enclosed.

☐ The attached English-language version of a search report or other action by a foreign patent office in a counterpart foreign application which cites document(s) \_\_\_\_\_ and which indicates the degree of relevance found by the foreign office is submitted to satisfy the requirement for a concise explanation of the relevance of the document(s), (see M.P.E.P., §609, p. 600-93).

☐ A concise explanation of the relevance of document(s) \_\_\_\_\_ is set forth as follows:

[insert concise explanation of relevance]

☐ A concise explanation of the relevance of document(s) \_\_\_\_\_ can be found on page(s) \_\_\_\_\_ of the specification.


☐ A concise explanation of the relevance of document(s) \_\_\_\_\_ can be found on the attached sheet.

☐ 4. Other information being provided for the Examiner's consideration follows:

5. In accordance with 37 C.F.R. §§1.97(g), 1.97(h), the filing of this IDS shall not be construed as a representation that a search has been made or as an admission that information cited in this IDS is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b). Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

6. Please charge any deficiency or other fees or credit any refund or overpayment to  
Deposit Account No. 01-0035.

Respectfully submitted,

  
\_\_\_\_\_  
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Form PTO-1449 (Rev. 7-80)		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket Control No. <b>206,588</b>		Serial No. <b>10/500,665</b>	
<div style="text-align: center;"> <b>LIST OF RELATED ART CITED BY APPLICANT</b>            (Use several sheets if necessary)         </div> <div style="position: absolute; left: 10px; top: 10px; border: 1px solid black; border-radius: 50%; padding: 5px; text-align: center;">             OIPE JC269              AUG 25 2005              PATENT &amp; TRADEMARK OFFICE           </div>				Applicant <b>LEONE ET AL.</b>		Filing Date <b>June 28, 2004</b>  Group <b>1615</b>	
<b>U.S. PATENT DOCUMENTS</b>							
*Examiner Initial	AA	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
	AB						
<b>FOREIGN PATENT DOCUMENTS</b>							
	AP	Document Number	Date	Country	Class	Subclass	Translation YES NO
<b>OTHER RELATED ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>							
	AR	Nicholson, "From Bench to Clinic with Apoptosis-Based Therapeutic Agents", <u>Nature</u> , Volume 407, 12 October 2000.					
	AS	Takayama et al., "Molecular Chaperone Targeting and Regulation by BAG Family Proteins", <u>Nature Cell Biology</u> , Vol. 3, October 2001.					
	AT	Shinichi Takayama et al., "An Evolutionarily Conserved Family of Hsp70/Hsc70 Molecular Chaperone Regulators", <u>The Journal of Biological Chemistry</u> , Vol. 274, No. 2, Pgs., 781-786, 1999.					
	AU	Doong et al., "CAIR-1/BAG-3 Forms an EGF-Regulated Ternary Complex with Phospholipase C-γ and Hsp 70/Hsc70, <u>Oncogene</u> , Vol. 19, pgs. 4385-4395 (2000).					
	AV	Jeong-Hwa Lee et al., "Bis, a Bcl-2-binding Protein that Synergizes with Bcl-2 in Preventing Cell Death", <u>Oncogene</u> , 18, pgs. 6183-6190 (1999).					
	AW	Quan Liao, "The Anti-Apoptotic Protein BAG-3 is Overexpressed in Pancreatic Cancer and Induced by Heat Stress in Pancreatic Cancer Cell Lines", <u>FEBS Letters</u> , 503 pgs. 151-157 (2001).					
	AX	Antoku et al., "Isolation of Bcl-2 Binding Proteins that Exhibit Homology with BAG-2 and Suppressor of Death Domains Protein", <u>Biochemical and Biophysical Research Communications</u> , 286, pgs. 1003-1010, (2001).					
	AY	Renz et al., "Rapid Extracellular Release of Cytochrome c is Specific for Apoptosis and Marks Cell Death in Vivo", <u>Blood</u> , Vol. 98, No. 5, (2001).					
	AZ	Kluck et al., "Cytochrome C Activation of CPP32-Like Proteolysis Plays a Critical Role in Xenopus Cell-Free Apoptosis System", <u>The Embo Journal</u> , Vol. 16, No. 15, pp. 4639-4649, (1997).					
Examiner				Date Considered			
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

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	AP	Document Number	Date	Country	Class	Subclass	Translation YES NO
<b>OTHER RELATED ART</b> <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>							
	AR	Koopman et al., "Annexin V for Flow Cytometric Detection of Phosphatidylserine Expression on B Cells Undergoing Apoptosis", <u>Blood</u> , Vol. 84, No. 5 (September 1994).					
	AS	Nicoletti et al., "A Rapid and Simple Method for Measuring Thymocyte Apoptosis by Propidium Iodide Staining and Flow Cytometry", <u>Journal of Immunological Methods</u> , 139, pgs. 271-279, (1991).					
	AT	Tassone et al., "CD36 is Rapidly and Transiently Upregulated On Phytohemagglutinin (PHA)-Stimulated Peripheral Blood Lymphocytes. Analysis by a New Monoclonal Antibody (UN 7)", <u>Tissue Antigens</u> , 51, pgs. 671-675 (1998).					
	AU	Romano et al., "Triggering of CD40 antigen Inhibits Fludarabine-Induced Apoptosis in B Chronic Lymphocytic Leukemia Cells", <u>Blood</u> , Vol. 92, No. 3, pgs. 990-995 (1998).					
	AV	Stavros C. Manolagas, "Manipulating Programmed Cell Death for Better Living", <u>Science's Stke</u> , <a href="http://www.stke.org/cgi/content/full/OC_sigtrans">www.stke.org/cgi/content/full/OC_sigtrans</a> ; (2001).					
	AW	Drissi, "C-Myc-Mediated Regulation of Telomerase Activity is Disabled in Immortalized Cells", <u>The Journal of Biological Chemistry</u> , Vol. 276, No. 32, Pgs. 29994-30001 (2001)					
	AX	Petit-Frere et al., "Apoptosis and Cytokine Release Induced by Ionizing or Ultraviolet B Radiation in Primary and Immortalized Human Keratinocytes" <u>Carcinogenesis</u> , Vol. 21, No. 6, pgs. 1087-1095, (2000).					
	AY	Brezden et al., "Differential Cell Death in Immortalized and Non-Immortalized Cells at Confluency", <u>Oncogene</u> , 12, pgs. 201-206, (1996)					
	AZ	Iordanov et al., "Differential Requirement for the Stress-Activated Protein Kinase/c-Jun NH <sub>2</sub> - Terminal Kinase in RNA Damage-Induced Apoptosis in Primary and in Immortalized Fibroblasts", <u>Molecular Cell Biology Research Communications</u> , 4, pgs 122-128 (2000).					
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<b>OTHER RELATED ART</b> <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>							
	AR	Marsden and Strasser, "Control of Apoptosis in the Immune System: Bcl-2, BH3-Only Proteins and More", <u>Annu. Rev. Immunol.</u> 21, pgs 71-105 (2003).					
	AS	Roth et al., "Bag-1 and Bcl-2 Gene Transfer in Malignant Glioma: Modulation of Cell Cycle Regulation and Apoptosis", <u>Brain Pathology</u> , 10, pgs. 223,-234 (2000)					
	AT	Zong et al., "BH3-Only Proteins that Bind Pro-Survival Bcl-2 Family members Fail to Induce Apoptosis in the Absence of Bax and Bak", <u>Genes and Development</u> , 15, pgs. 1481-1486, (2001)					
	AU	Gewirtz, "Oligonucleotide Therapeutics: Clothing the Emperor", <u>Current Opinion in Molecular Therapeutics</u> , Vol. 1, No. 3, (1999).					
	AV	Opalinska et al, "Nucleic-Acid Therapeutics: Basic Principles and Recent Applications", <u>Nature Publishing Group</u> , Volume 1, pgs, 503-514 (July 2002)					
	AW	Keah et al., "Direct Synthesis and Characterisation of Multi-Dendritic Peptides for Use as Immunogens", <u>J. Peptide Res.</u> 51, pgs. 2-8, (1998).					
	AX	Tam, "Synthetic Peptide Vaccine Design: Synthesis and Properties of a High-Density Multiple Antigenic Peptide System", <u>Proc. National Academy, Sciences</u> , Vol. 85 pgs. 5409-5413, (1988).					
	AY	Ota et al., "Cellular Processing of a Multibranched Lysine Core with Tumor Antigen Peptides and Presentation of Peptide Epitopes Recognized by Cytotoxic T Lymphocytes on Antigen-Presenting Cells", <u>Cancer Research</u> , Vol. 62, pgs 1471-1476, (2002).					
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